NOV 7 2002

510(k) Summary

510(k) Number: **K021434**
Contact Person: Ann Waterhouse, Regulatory Affairs Specialist
Date Prepared: December 13, 2001

Trade/Proprietary Name: Arthrex Fiberwire™ USP suture family
Product Code: GAT
Classification Name: Suture, Non-absorbable, Synthetic, Polyester
Predicate Devices: Arthrex K010673, Arthrex K012923, Grams American Suture K003590 Arthrex K012923, ARC Medical Supplies K000540, Genzyme Surgical Product K001434.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Intended Use:

Fiberwire™ USP sizes are intended for use in approximation or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Description:

Arthrex, Inc. Fiberwire™ suture consists of a family of varying length, needle type, and standard USP diameter sutures. They are made of long chain polyesters which are braided and sterilized for surgical use. They are available in dyed and non-dyed varieties, with or without needles.

Substantial Equivalence:

The Arthrex, Inc. Fiberwire™ Family USP suture(s) are substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Arthrex suture and predicate devices do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Anthrex, Inc.
Ann Waterhouse
Regulatory Affairs Specialist
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K021434
Trade/Device Name: Anthrex Fiberwire™ Family, USP Size Sutures
Regulation Number: 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: August 15, 2002
Received: August 16, 2002

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K021434**

Device Name: **Arthrex Fiberwire™Family, USP size sutures**

Indications for Use:

Fiberwire™ USP sizes are intended for use in approximation or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Option Format 3-10-98)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021434